DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

WARNING LETTER
VIA EXPRESS

OCT 24 2000

Mr. Kirk Foley
CEO & Owner
Activa Brand Products
6845 Devand Drive
Mississauga, Ontario
L5T 1L4 Canada

Dear Mr. Foley:

During the initial inspection of your firm located in Charlottetown, P.E.I., Canada, on September 5-6, 2000 our investigator determined that your firm manufactures needleless insulin injectors. These products are devices as defined by Section 201(h) of the Federal, Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulation, as specified in Title 21, Code of Federal Regulation (CFR), Part 820, as follows:

1. Failure to adequately establish procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, as required by 21CFR 820.198(a). For example:

   a. Other than the reference to handling complaints in QAP 14, Corrective and Preventive Action, your firm lacks complaint handling procedures. Specific procedures for complaint handling need to be established according to 21 CFR 820.198. These procedures must contain provisions for evaluation of complaints to determine medical device reports (MDR) reportability [21 CFR 820.198(a)(3)].
   b. Complaints are not reviewed by management and quality system personnel.

2. Failure to adequately establish and maintain an adequate organizational structure to ensure that devices are designed and produced in accordance with the requirements in 21 CFR 820, as required by 21 CFR 820.20(b). For example, the management representative is a Quality Control Supervisor of a sister/supplier company.

3. Failure to ensure that quality system requirements are effectively established and effectively maintained in accordance with 21 CFR 820, as required by 21 CFR 820.20(b)(3)(i). For example, your firm has a quality manual containing several quality system procedures; however, the procedures have not been implemented.

4. Failure for management with executive responsibility to review the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency according to established procedures to ensure that the quality system satisfies the requirements of this part and the manufacturer's established quality policy and objectives, as required by 21 CFR 820.20(c). For example, no management reviews have been conducted.

5. Failure to conduct quality audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system, as required by 21 CFR 820.22. For example, your firm has procedures for quality audits; however, audits have not been performed.

6. Failure to have sufficient personnel with the necessary education, background, training, and experience to assure that all activities required by 21 CFR 820 are correctly performed, as required by 21 CFR 820.25(a). For example, only one individual is responsible for assembly of the injectors, quality control testing, final acceptance, and customer relations including complaint handling.

7. Failure to establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation, as required by 21 CFR 820.30(i). For example, your firm lacks procedures for design changes.

8. Failure to maintain process control procedures, which include documented instructions, standard operating procedures, and methods that define and control the manner of production, as required by 21 CFR 820.70(a). For example, there were no assembly/production procedures available on-site.

9. Failure to adequately establish and maintain procedures to ensure that equipment is routinely calibrated, inspected, checked, and maintained, and failure to document these activities, as required by 21 CFR 820.72(a). For example:

    a. QAP 11, Control of Inspection, Measuring and Test Equipment, is incomplete, in that it does not require that inspection, measuring and test equipment be inspected. The procedures should also include provisions for handling, preservation, and storage of equipment, so that its accuracy and fitness for use are maintained.

    b. The calibration and maintenance activities for the oscilloscope have not been documented.

10. Failure to adequately establish and maintain the requirements, including quality requirements, that must be met by suppliers, as required by 21 CFR 820.50(a). For example, QAP 6, Purchasing, states that "All materials and services purchased must conform to contractual requirements and to specified standards." However, your firm does not have a contractual relationship with any of it's suppliers.

11. Failure to establish and maintain records of acceptable suppliers, contractors, and consultants, as required by 21 CFR 820.50(a)(3). For example, QAP 6, Purchasing, requires an approved vendor list; however, your firm lacks such a list.

12. Failure to adequately establish and maintain procedures for acceptance activities, as required by 21 CFR 820.80(a). For example, your firm lacks procedures for acceptance of receiving activities, in-process activities, and final product activities.

In addition to the above observations, we have concern regarding the usage of the word 'sterilize' in the Operation and Instruction Manual. This manual states to sterilize the device with rubbing alcohol. Rubbing alcohol is not a sterilant, but a disinfectant. Therefore, it is suggested that you change the word 'sterilize' to disinfect.'

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the form FDA 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance system. You are responsible for investigating and determining the causes of the violations identified by the Food and Drug Administration. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Please notify this office in writing within 15 days of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make correction to any underlying systems problems necessary to assure that similar violations will not recur. Please include any and all documentation to show that adequate correction has been achieved. In the case of future corrections, an estimated date of completion, and documentation showing plans for correction, should be included with your response to this letter.

If documentation is not in English, please provide an English translation to facilitate our review. Please address your response and any questions to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Enforcement II, General Hospital Devices Branch, HFZ-333, 2098 Gaither Road, Rockville, Maryland 20850, to the attention of Ms. Carolyn Niebauer.

Should you require any assistance in understanding the contents of this letter, do not hesitate to contact Ms. Leslie E. Dorsey at the letterhead address or at 301.594.4618 or FAX 301.594.4638.

Sincerely yours,

Larry Spears
Acting Director
Office of Compliance
Center for Devices and Radiological Health